(1) ''For the removal of corns and calluses.''

(2) In addition to the information identified in paragraph (b)(1) of this section, the labeling of the product may contain the following statement: ''Relieves pain by removing corns and calluses.''

(c) *Warnings.* The labeling of the product contains the following warnings under the heading ''Warnings'':

(1) *For products containing any ingredient identified in § 358.510.* (i) ''For external use only.''

(ii) ''Do not use this product on irritated skin, on any area that is infected or reddened, if you are a diabetic, or if you have poor blood circulation.''

(iii) ''If discomfort persists, see your doctor or podiatrist.''

(2) *For any product formulated in a flammable vehicle.* (i) The labeling should contain an appropriate flammability signal word, e.g., ''extremely flammable,'' ''flammable,'' ''combustible,'' consistent with 16 CFR 1500.3(b)(10).

(ii) ''Keep away from fire or flame.''

(3) *For any product formulated in a volatile vehicle.* ''Cap bottle tightly and store at room temperature away from heat.''

(4) *For any product formulated in a collodion-like vehicle.* (i) ''If product gets into the eye, flush with water for 15 minutes.''

(ii) ''Avoid inhaling vapors.''

(d) *Directions.* The labeling of the product contains the following information under the heading ''Directions'':

(1) *For products containing salicylic acid identified in § 358.510(a).* ''Wash affected area and dry thoroughly.'' (If appropriate: ''Cut plaster to fit corn/callus.'') ''Apply medicated plaster. After 48 hours remove the medicated plaster. Repeat this procedure every 48 hours as needed for up to 14 days (until corn/callus is removed).'' (Optional: ''May soak corn/callus in warm water for 5 minutes to assist in removal.'')

(2) *For products containing salicylic acid identified in § 358.510(b).* ''Wash affected area and dry thoroughly. Apply'' (select one of the following, as appropriate: ''one drop'' or ''small amount'') ''at a time with'' (select one of the following, as appropriate: ''applicator'' or ''brush'') ''to sufficiently cover each corn/callus. Let dry. Repeat this procedure once or twice daily as needed for up to 14 days (until corn/callus is removed).'' (Optional: ''May soak corn/callus in warm water for 5 minutes to assist in removal.'')

(e) The word ''physician'' may be substituted for the word ''doctor'' in any of the labeling statements in this section.

[55 FR 33261, Aug. 14, 1990, as amended at 57 FR 44494, Sept. 28, 1992]

Subpart G—Pediculicide Drug Products

SOURCE: 58 FR 65455, Dec. 14, 1993, unless otherwise noted.

§ 358.601 Scope.

(a) An over-the-counter pediculicide drug product in a form suitable for topical application is generally recognized as safe and effective and is not misbranded if it meets each condition in this subpart and each general condition established in § 330.1 of this chapter.

(b) References in this subpart to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.

§ 358.603 Definition.

As used in this subpart:

Pediculicide drug product. A drug product for the treatment of head, pubic (crab), and body lice.

§ 358.610 Pediculicide active ingredients.

The active ingredients of the product consist of the combination of pyrethrum extract (providing a concentration of pyrethrins of 0.17 to 0.33 percent) with piperonyl butoxide (2 to 4 percent) in a nonaerosol dosage formulation.

[63 FR 43303, Aug. 13, 1998]

§ 358.650 Labeling of pediculicide drug products.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as a ''pediculicide (lice treatment)'' or ''lice treatment.''